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\* DMQRP's State Contract Policy For Training MQSA Inspectors and Assigning Inspection Equipment

The mammography inspection program has reached a maintenance level for the number of trained State and FDA inspectors to conduct annual inspections of certified mammography facilities throughout the U.S. under the Mammography Quality Standards Act (MQSA).

#### BACKGROUND

In 1996, the Division of Mammography Quality and Radiation Programs (DMQRP) established and publicized a policy that outlined its rationale for determining the number of inspectors per State necessary to cover the number of facilities located within that State. DMQRP has since revisited its policy, evaluated its experience with inspections over the last few years, and has determined that the original position regarding the number of inspectors to be trained remains valid.

#### POLICY

Since establishing this policy, States have raised questions about the formula used by the Food and Drug Administration (FDA) to determine the optimum number of inspectors within a State. As a reminder and for your future reference, we are providing you with our policy which sets upper limits on the number of inspectors per State. These limits should not be interpreted as a goal or requirement under State contracts.

In setting limits on the number of inspectors trained per State, DMQRP considered the following issues: (1) training costs charged to State contracts, including travel and per diem for Courses I through III and associated weeks of salary per inspector throughout the training; (2) inspector equipment costs (inspection kit plus laptop computer, and MDH with mammography probe); (3) training costs incurred by DMQRP for training facilities, speakers, materials, staff time and effort; (4) the minimum number of inspections that should be performed by an inspector each year to maintain his/her proficiency (allowing that if too many inspectors are trained, some may not be able to remain active and qualified); (5) the cost in time and effort incurred by DMQRP for inspector continuing education and annual audits, updating inspectors, and addressing inspector needs and questions (this commitment increases as the number of inspectors increases); and, (6) a legitimate need to train supervisors or program managers and back-up inspectors to cover State turnover or additional facilities throughout the year.

For training purposes, we estimated that an inspector could complete two facility inspections per week, or 100 inspections per year (2 facilities x 50 weeks). This estimate has proven accurate, with some inspectors completing as many as five facilities per week when working full-time on MQSA. Therefore, we will continue to allow each contract State to have trained (at FDA expense) up to one inspector per 50 certified facilities, plus one back-up inspector. Training slots for each State will be provided on a one-for-one priority basis as inspectors leave the State mammography program.

States may choose to use inspectors for mammography inspections on a full-time basis and, therefore, may only need one inspector per 100-125 facilities. Additional inspector training (beyond the back-up inspector) will be an option pending availability of training openings and at the expense of the State.

#### CHANGE IN EQUIPMENT ISSUANCE

Beginning immediately due to budgetary constraints, DMQRP will supply the back-up inspector with the basic inspector kit, but will not provide him/her with a laptop computer or an MDH. Furthermore, DMQRP will not issue any equipment to inspectors who exceed the numbers allowed per State nor supply supervisors and program managers with inspection equipment. Currently, there are cases where back-up and excess inspectors are fully equipped. To maintain consistency with this equipment change, we will begin to notify the States that will require the return of extra equipment. Since back-up inspectors will not have a laptop assigned to them, FDA is requesting that those inspectors who do have a laptop, work closely with MQSA back-up inspectors by providing them with all e-mail messages and policy communications. For further clarification, in situations where an MQSA inspector leaves one State to work in another State we will recall their equipment and evaluate the State's needs and reissue equipment according to the new policy.